

9111-14

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning

Self-Adhesive Cutaneous Electrodes

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of Rhythmlink International, LLC’s self-adhesive cutaneous electrode. Based upon the facts presented, CBP has concluded that the country of origin of the self-adhesive cutaneous electrode is the United States for purposes of U.S. Government procurement.

DATES: The final determination was issued on January 29, 2019. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination no later than [insert 30 days from date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: James Kim, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade (202) 325-0158.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on January 29, 2019, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR Part 177, subpart B), CBP issued a final determination concerning the country of origin of Rhythmlink International, LLC’s self-adhesive cutaneous electrode, which may be offered to the U.S. Government under an undesignated government procurement contract. This final

determination, HQ H300743, was issued under procedures set forth at 19 CFR Part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511-18). In the final determination, CBP concluded that the assembly and processing in China do not result in a substantial transformation. Therefore, the country of origin of Rhythmlink International, LLC's self-adhesive cutaneous electrode is the United States for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the *Federal Register* within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the *Federal Register*.

Dated: January 29, 2019

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade

HQ H300743

January 29, 2019

OT:RR:CTF:VS H300743 JK

CATEGORY: Origin

David S. Robinson
Nexsen Pruet, PLLC
4141 Parklake Avenue
Suite 200

Raleigh, NC 27612

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Self-Adhesive Cutaneous Electrode; Substantial Transformation

Dear Mr. Robinson:

This is in response to your letter, dated September 10, 2018, requesting a final determination on behalf of Rhythmink International, LLC (Rhythmink) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (CBP) Regulations (19 C.F.R. Part 177).

This final determination concerns the country of origin of various self-adhesive cutaneous electrodes. As a U.S. importer, Rhythmink is a party-at-interest within the meaning of 19 C.F.R. § 177.22(d)(1) and is entitled to request this final determination. In addition, you have requested a country of origin determination for marking purposes. Samples were submitted with your request.

FACTS:

Rhythmink is headquartered in Columbia, North Carolina and manufactures and distributes medical devices. It seeks a country of origin determination for purposes of government procurement for two types of self-adhesive cutaneous electrodes, marketed as “Disposable Stimulating Sticky Pad Surface Electrodes” and “Disposable Recording Sticky Pad Surface Electrodes.” You indicate that these products are designed and manufactured specifically for electrocardiogram (ECG) and electromyogram (EMG) monitoring applications. The catalog that you submitted indicates that the electrodes are pre-gelled and especially formulated to perform specific functions. You also state that these products are regulated by the U.S. Food & Drug Administration (FDA) under the category of “cutaneous electrode,” which is defined as “an electrode that is applied directly to a patient’s skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.” *See* 21 C.F.R. § 882.1320.

Each self-adhesive cutaneous electrode consists of a “sticky pad,” composed of electrically conductive hydrogel laminated onto conductive plastic and fabric backing, which is attached to a leadwire with a miniscule amount of glue. Rhythmink sells its self-adhesive cutaneous electrodes in single (one pad) and paired (two pads connected) models with varying lengths and styles, and end users can customize the color of the connecting leadwire. You indicate that the functionality of the Sticky Pad Surface Electrode is common to all lengths and is unchanged by the color of the pre-connected leadwire. The Sticky Pad Surface Electrode also comes in varying pad sizes; the larger the pad size, the greater the conductivity (but lower the specificity) of the electrical signals. The leadwire acts as an electrical conductor that transfers low voltage electrical signals from the electrode to medical diagnostic equipment. However, you also state

that other varieties of cutaneous electrodes are available that are not pre-connected to a leadwire. Such cutaneous electrodes may connect to a leadwire by using alligator clips and other removable connectors.

You state that RhythmLink conducts all of the engineering and design of its self-adhesive cutaneous electrode in the United States. RhythmLink purchases the hydrogel used in its self-adhesive cutaneous electrodes from a manufacturer in bulk roll form. The hydrogel, including all of its components, is manufactured entirely in the United States and specifically developed as a sensing or stimulating gel for use in medical electrode-related applications in cutaneous electrodes. You state that the hydrogel is manufactured in such a way as to serve as a metal-electrolyte interface, through which current flow within a patient becomes electron flow in the electrode and leadwire. You also state that the quality of the signals generated depends, in part, on the electrical characteristics of the electrode assembly, which is largely determined by the formula of the hydrogel used.

The components used to formulate the hydrogel include deionized water, salts, and a gelling agent. These components are mixed together until homogenous, forming a conductive “soup.” The pH of the mixture is adjusted to a very specific level. The mixture is then cast to a specific thickness in sheet form directly onto a clear plastic backing material on a conveyor system, slowly moving along under specific environmental conditions (e.g., temperature and humidity) to allow the gel to set. At the end of the line, thin plastic film is pressed onto the gel as a protective layer prior to rolling the hydrogel product around heavy cardboard tubes in 300 foot lengths. You indicate that the hydrogel has a limited shelf life, after which it ceases to be a medical product. The bulk roll hydrogels are then shipped to China for further processing.

Korean-origin leadwire is also shipped to China. The leadwire is a commercially available 26-gauge twisted copper wire comprising 19 strands of 38-gauge copper wire with medical grade PVC covering. The leadwire is available in a total of 26 color options. The Korean supplier of this wire cuts the wire, crimps a socket pin, attaches a connector to one end of the wire, and ships the wire to China.

In China, the bulk roll hydrogel is first laminated to U.S.-origin conductive plastic and Chinese-origin fabric backing, in a process that occurs in one second for the surface area required to punch out a single self-adhesive cutaneous electrode. Then the laminated bulk roll hydrogel is mechanically die cut one pad at a time, taking less than a second per pad. Subsequently, the Korean-origin leadwire is attached to the pad using U.S.-origin glue, “sandwiching” it between the conductive plastic and fabric backing in a process that takes less than four seconds per electrode. Finally, the finished self-adhesive cutaneous electrodes are inserted into plastic pouches and cardboard packaging for shipment to the United States.

In the United States, the finished products are subject to sterilization and a randomized sampling and testing protocol prior to sale.

ISSUE:

What is the country of origin of the self-adhesive cutaneous electrode for purposes of U.S. Government procurement?

LAW AND ANALYSIS:

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 C.F.R. § 177.21 *et seq.*, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. § 2511 *et seq.*) (TAA).

Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B):

An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 C.F.R. § 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with Federal Acquisition Regulations. *See* 19 C.F.R. § 177.21. In this regard, CBP recognizes that the Federal Acquisition Regulations restrict the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 C.F.R. § 25.403(c)(1). The Federal Acquisition Regulations define “U.S.-made end product” as:

. . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

The regulations define a “designated country end product” as:

WTO GPA [World Trade Organization Government Procurement Agreement] country end product, an FTA [Free Trade Agreement] country end product, a least developed country end product, or a Caribbean Basin country end product.

A “WTO GPA country end product” is defined as an article that:

- (1) Is wholly the growth, product, or manufacture of a WTO GPA country; or
- (2) In the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed. The term refers to a product offered for purchase under a supply contract, but for purposes of calculating the value of the end product includes services (except transportation services) incidental to the article, provided that the value of those incidental services does not exceed that of the article itself.

48 C.F.R. § 25.003. We note that Korea is a WTO GPA country, but China is not.

A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact. *See United States v. Gibson-Thomsen Co.*, 27 C.C.P.A. 267 (1940); *National Juice Products Association v. United States*, 628 F. Supp. 978 (CIT 1986).

In order to determine whether a substantial transformation occurs when components of various origins are assembled into completed products, CBP considers the totality of the circumstances and makes such determinations on a case-by-case basis. The country of origin of the item’s components, extent of the processing that occurs within a country, and whether such processing renders a product with a new name, character, and use are primary considerations in such cases. No one factor is decisive; the key issue is the extent of operations performed and whether the parts lose their identity and become an integral part of the new article. *Belcrest Linens v. United States*, 573 F. Supp. 1149 (CIT 1983), *aff’d*, 741 F.2d 1368 (Fed. Cir. 1984). Assembly operations that are minimal or simple, as opposed to complex or meaningful, will generally not result in a substantial transformation. *See* C.S.D. 80-111, C.S.D. 85-25, C.S.D. 89-110, C.S.D. 89-118, C.S.D. 90-51, and C.S.D. 90-97. Additionally, factors such as the resources expended on product design and development, extent and nature of post-assembly inspection and testing procedures, and the degree of skill required during the actual manufacturing process may be relevant when determining whether a substantial transformation has occurred.

The Court of International Trade has also looked at the essential character of an article to determine whether its identity has been substantially transformed through

assembly or processing. For example, in *Uniroyal, Inc. v. United States*, 3 CIT 220, 225, 542 F. Supp. 1026, 1030 (1982), *aff'd*, 702 F.2d 1022 (Fed. Cir. 1983), the court held that imported shoe uppers added to an outer sole in the United States were the “very essence of the finished shoe” and thus the character of the product remained unchanged and did not undergo substantial transformation in the United States. Similarly, in *National Juice Products Association v. United States*, 10 CIT 48, 61, 628 F. Supp. 978, 991 (1986), the court held that imported orange juice concentrate “imparts the essential character” to the completed orange juice and thus was not substantially transformed into a product of the United States.

For products used in medical-related applications, we have held that no substantial transformation occurs when the critical components which impart the essential character of the product subsequently undergo simple assembly and processing. In HQ H248851, dated July 8, 2014, CBP held that an Israeli-origin CO₂ tube was not substantially transformed in China when cut to length and attached to four other components from Israel and China. CBP found that the CO₂ tube performed the essential function of the finished product, which was the delivery of breath for monitoring the CO₂ level in a patient’s breath. By way of the assembly process in China, the CO₂ tube was attached to other components that facilitated its function and did not lose its individual identity in the process.

Similarly, in HQ 560613, dated October 28, 1997, Customs, a predecessor of CBP, held that U.S.-origin components were not substantially transformed in Ireland when made into a pregnancy test kit. The test kit was made from the following U.S. components: top and bottom housing, paper, antibody, wick, laminate, and nitrocellulose. In addition, a splash guard from Ireland and rayon from Germany were used. The critical components of the pregnancy test kit were found to be the three U.S.-origin antibodies. Customs recognized that the U.S.-origin components imparted the essential character of the pregnancy test kit and that the simple assembly of placing the antibodies onto the rayon membrane, and subsequent assembly of the strips into a plastic housing, did not result in a substantial transformation.

In H259473, dated June 30, 2015, CBP found that a single use negative pressure wound therapy system, comprised of a pump from China and two dressings from the United Kingdom, was of U.K.-origin due to the U.K.-origin of the dressings and the programming and final assembly of the pump occurring in the U.K. CBP found that the unique dressing was the “enabling technology” that provided the essential therapeutic elements for wound healing to the medical instrument. In addition, CBP noted that the medical instrument could only be used with the dressings included with the system.

Based on the information provided in your letter and consistent with CBP rulings cited above, we note that the majority of the components of the self-adhesive cutaneous electrode are of U.S. or WTO GPA country origin, including the U.S.-origin hydrogel, conductive plastic, and glue, and the Korean-origin leadwire. Only the fabric backing, which merely adds strength to the leadwire connection, is of Chinese-origin. More

importantly, we find that the electrically conductive hydrogel, manufactured entirely in the United States, performs the essential function of the finished product, which is to provide the means whereby electrical activity in the body is recorded by the input circuits of an EEG/EMG machine, or electrical impulses are generated when used with stimulating equipment. The hydrogel's adhesive properties are essential to allowing the product to function as a self-adhesive cutaneous electrode. As indicated in your letter, the hydrogel used in this product is dedicated for use in cutaneous electrodes, as the chemical and mechanical properties of the hydrogel dictate its single intended use in medical electrode-related applications. Furthermore, the product ceases to be a medical product once the shelf life of the hydrogel has been exceeded. Accordingly, we find that the U.S.-origin hydrogel imparts the essential character of the self-adhesive cutaneous electrode.

Regarding the assembly and processing that occurs in China, we note that these constitute relatively simple and minor operations involving highly repetitive, low-skill functions. The lamination of the hydrogel onto the conductive plastic and fabric backing, the mechanical die cutting of the pad, and the gluing of the leadwire occur in less than six seconds per electrode. In contrast, we recognize that all of the engineering and design of the self-adhesive cutaneous electrode occurs in the United States. While the conductive plastic, fabric backing and leadwire facilitate the product's functionality, the hydrogel itself remains unchanged by the Chinese assembly and processing and continues to provide the essential function of the FDA-regulated "cutaneous electrode" product. Consequently, we find that the self-adhesive cutaneous electrode is not substantially transformed by the assembly and processing that occur in China.

With regard to your marking question, Section 304 of the Tariff Act of 1930, as amended (19 U.S.C. § 1304), provides that, unless excepted, every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit in such a manner as to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article. The regulations implementing the country of origin marking requirements and exceptions of 19 U.S.C. § 1304, along with certain marking provisions of the Harmonized Tariff Schedule of the United States (19 U.S.C. § 1202), are set forth in 19 C.F.R. Part 134. "Country of origin" is defined, in relevant part, as: the country of manufacture, production, or growth of any article of foreign origin entering the United States. 19 C.F.R. § 134.1(b). Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the "country of origin" within the meaning of this part[.]

For purposes of marking, the same substantial transformation analysis discussed above applies in this case. Accordingly, the self-adhesive cutaneous electrodes which are processed in China are products of the United States. Because the electrodes are products of the United States that are exported and returned without undergoing a substantial transformation, they are excepted from country of origin marking

requirements pursuant to 19 C.F.R. § 134.32(m). Please note that if you wish to mark the self-adhesive cutaneous electrodes or the packaging containing these products to indicate that they are “Made in the USA”, the marking must comply with the requirements of the Federal Trade Commission (FTC). We suggest that you direct any questions on this issue to the FTC.

HOLDING:

Based on the information provided, the country of origin of the self-adhesive cutaneous electrode for U.S. government procurement purposes is the United States.

Notice of this final determination will be given in the *Federal Register*, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.30, any party-at-interest may, within 30 days after publication of the *Federal Register* notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Alice A. Kipel
Executive Director
Regulations and Rulings
Office of Trade